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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/761,596

01/21/2004

Wilfred Wayne Lauth

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08/03/2006

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EXAMINER

DELACROIX MUIRHEI, CYBILLE

ART UNIT

PAPER NUMBER

1614

DATE MAILED: 08/03/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/761,596

Applicant(s)

LAUTT, WILFRED WAYNE

Examiner

Cybille Delacroix-Muirheid

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 08 March 2006.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 11-13 and 17 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 11-13 and 17 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 21 January 2004 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____.
- 4) ☒ Interview Summary (PTO-413)
Paper No(s)/Mail Date. 02/07/06
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

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Detailed Action

1. Claims 11-13, 17 are rejected under 35 U.S.C. 103(a) as being unpatentable over Adams et al., 6,165,975 and Papandreou et al., 6,171,232 and Salzman et al., 5,958,427 and Klokke-Bethke et al., 5,370,862 and Veronesi et al., 5,580,576.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Response to Applicant's Remarks

The following is responsive to applicant's remarks received March 8, 2006.

Claims 1-10 and 14-16 are cancelled. Claims 11-13 and 17 are currently pending.

Applicant's arguments traversing the previous claim rejection under 35 USC 103(a)(see paragraph 1 above) set forth in paragraph 1 of the office action mailed Sep. 9, 2005 have been considered but are not found to be persuasive.

Said rejection is maintained essentially for the reasons given previously in the office action mailed Sep. 9, 2005 with the following additional comment.

Applicant argues that the instant case is distinguished from In re Ngai and In re Gulack, and that the instructional materials are functionally related to the composition in the instant kit claims. In Ngai it was not contested that the prior art taught (a) each of the physical elements to Ngai's kit, for use in amplifying RNA, as well as (b) instructions for using those elements for amplifying RNA, i.e, for achieving the same function that Ngai taught. Ngai taught an improved methodology.

In contrast, in the instant application there is no prior art teaching (a) any of the physical elements of the instantly claimed kit for use in treating insulin resistance, nor any prior art

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teaching (b) instructions for using those physical elements for treating insulin resistance, i.e., instructions for achieving the same function as the instant applicant teaches, with the physical elements that the instant applicant teaches. The prior art does not teach or motivate one of ordinary skill in the art to use the nitric oxide donor and/or nitric oxide agonist compound(s) of the kit to produce the desired results. Applicant submits that as far as the claimed invention is concerned, drugs sold in modern society depend on, and are functionally tied to, the printed matter sold with the drug.

In addressing In re Gulack and the use of printed matter, the court determined that “the critical question is whether there exists any new and unobvious functional relationship between the printed matter and the substrate.” Applicant respectfully submits that in the instantly claimed kit the instructions are functionally related to the composition(s). One does not, and indeed cannot sell drugs without instructions for use. In any event, if one did sell drugs without instruction for their use, the functionality of the drug would be lost, that is to say a pharmacy filled with unlabelled drugs would not be functional. Applicant contends there is no case law or statutory law, including In re Ngai, stating that each element in a kit claim must physically interact with the other elements, i.e., that the instructions must physically interact with the other elements. Ngai only states that there must be functionality to the printed matter. Applicant has established that such functionality exists in the instant case.

Given that the instructions in the instantly claimed kit are functionally related to the rest of the kit's elements, the content of these instructions must be considered relevant to distinguishing the instantly claimed kit from the prior art. Since none of the cited prior art discloses or teaches instructions for oral administration to ameliorate symptoms of insulin

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resistance, Applicant respectfully argues that the instantly claimed kit is novel and inventive over the prior art.

Finally, regarding the requirement by the Examiner that elements of a kit must interact, Applicant submits the following case. In Ex parte Adams and Ferrari, 177 U.S.P.Q. 21, Patent Office Board of Appeals, 1974, (copy is enclosed for examiner's convenience), the Board of Appeals considered a rejection from an Examiner in a claim directed to the combination of a fireplace having a metallic surface on its fire chamber, a damper in its flue, and a magnet attachable to the metallic surface for indicating the closed condition of the damper. The Examiner rejected the claim on the basis that there was no co-operation present between the fireplace and the magnetic pendant except for what the user may mentally choose to indicate. The Board reversed the decision of the Examiner, and held specifically that "[w]e know of no requirement in the statute of direct mechanical interaction between the elements of a combination. As long as the overall result has utility and is unobvious, the elements of a patentable combination may function independently.

In the instant application, there is no direct mechanical interaction between the elements of the combination in the kit, however the elements of the instant kit do function in coordination, i.e., the medicine is not functional without the directions, and the directions are useless without the medicine.

Said arguments have been considered but are not found to be persuasive.

The examiner respectfully maintains that the claimed kits are obvious in view of the prior art. In In re Haller 73 USPQ 403 (CCPA 1947), it is held that application of printed matter to old article cannot render the article patentable. In the opinion text of In re Haller, it is stated that:

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“[w]hether the statement of intended use appears merely in the claim or in label on the product is immaterial so far as the question of patentability is concerned. . . In accordance with the patent statutes, an article or composition of matter, in order to patentable, must not only be useful and involve invention, but must also be new. If there is no novelty in an article or composition itself, then a patent cannot be properly granted on the article or composition, regardless of the use for which it is intended. The difficulty is not that there can never be invention in discovering a new process involving the use of an old article, but that the statutes make no provision for patenting of an article or composition which is not, in and of itself, new.” In the claimed kits of the instant application, there is no novelty in the compositions comprising a nitric oxide donor and/or a nitric oxide agonist compound. Please refer again to paragraph 1 of the office action mailed Sep. 9, 2005.

Also see In re Venezia 189 USPQ 49 (CCPA 1976), where kits are drawn to the structural attributes of *interrelated* component parts and not to activities that may or may not occur. Further, In re Miller 164 USPQ 46 (CCPA 1969) and In re Gulack (CAFC) 217 USPQ 401 relate to a mathematical device and to a measuring cup respectively as well as In re Ngai, 70 USPQ2d 1862 (CAFC 2004). In each of these cases, the printed matter is considered a patentable distinction because the *function of the device depends upon the printed matter itself*, which is a part of the substrate. Without the printed indicia or numbers, the substrates lose their function. Such is not the case with the instantly claimed kits. The compositions, in the kit, containing nitric oxide donor and/or nitric oxide agonists can function as active, effective drugs even in the absence of the instructional material. The claimed kit remains fully functional absent the labeling or printed instructions for use.

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Moreover, the instructions for use included in a kit or article manufacture constitute an “intended use” for that kit or article of manufacture. Intended use does not impart patentable weight to a product. See MPEP 2111.03: Intended use recitations and other types of functional language cannot be entirely disregarded. However, in apparatus, article and composition claims, intended use must result in a *structural difference* between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim. *In re Casey*, 370 F.2d 576, 152 USPQ 235 (CCPA 1967); *In re Otto*, 312 F.2d 937, 938, 136 USPQ 458, 459 (CCPA 1963).

In the instant case, the kit claims are drawn to a known composition, i.e. a nitric oxide donor compound and/or a nitric oxide agonist compound, which further comprises instructions for using the composition to ameliorate the symptoms of insulin resistance, by oral administration of the compound(s). The intended use, which is recited on the inserted instructional material, lacks a functional relationship with the claimed compound(s) because the insert does not physically or chemically affect the chemical nature of the nitric oxide donor compound and/or a nitric oxide agonist compound. Moreover, the skilled artisan can still use the known compositions of the kit for other purposes. Therefore the claimed kits are unpatentable over the prior art, because the composition(s) within the kit function equally effectively with or without the instructions. No functional relationship exists between the instructions for use and the composition.

Finally, the examiner respectfully submits that applicant’s reliance on Ex parte Adams and Ferrari is misplaced. The facts of that case are clearly distinguishable from those involved in

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the instant application because none of the appealed claims in Ex parte Adams and Ferrari involved printed matter. Notwithstanding, the examiner disagrees with applicant's contention that the composition and the instructional material of the claimed kits function in coordination such that the claimed composition does not function without the instructions and the instructions are useless without the claimed composition. If the compounds that make up the compositions in the claimed kits were administered to a patient, they would continue to exert a pharmaceutical effect. In other words, as stated above, the claimed nitric oxide donor and/or nitric oxide agonists can function as active, effective drugs even in the absence of the instructional material.

The rejection is respectfully maintained.

Conclusion

Claims 11-13, 17 stand rejected.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).


A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the mailing date of this final action.

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to **Cybille Delacroix-Muirheid** whose telephone number is **571-272-0572**. The examiner can normally be reached on Mon-Thurs. from 8:30 to 6:00 as well as every other Friday from 9:30-6:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, **Ardin Marschel**, can be reached on **571-272-0718**. The fax phone number for the organization where this application or proceeding is assigned is **571-273-8300**.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

CDM 
July 26, 2006

 7/29/06
ARDIN H. MARSCHEL
SUPERVISORY PATENT EXAMINER